

Message

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Subject: News Update: EPA Research Office Nominee Downplays GOP Attacks On Agency Science (InsideEPA)

Daily News

EPA Research Office Nominee Downplays GOP Attacks On Agency Science

Posted: August 07, 2015

President Obama's long-pending nominee to head EPA's Office of Research & Development (ORD) is pushing back on Republican senators' attacks on agency science, defending against concerns about potential conflicts of interest and other alleged flaws in scientific data that EPA often uses as the basis for its regulatory decisions.

In a July 30 response to questions from GOP members of the Senate Environment & Public Works Committee (EPW), nominee Thomas Burke says that existing agency procedures and a host of planned future actions address concerns about inadequate science. And he vows to follow through with improvements to ORD's work, such as a plan to prioritize Integrated Risk Information System (IRIS) chemical risk assessments.

Burke's answers, recently obtained by *Inside EPA*, offer few concessions to Republican critics of the agency's science, and it is unclear whether the response will help shift his stalled nomination.

The ORD nominee is one of several nominations for top agency positions that have been pending in the Senate for weeks, including acting EPA air chief Janet McCabe to head the Office of Air & Radiation on a

permanent basis and *de facto* agency water chief Ken Kopocis to be the Office of Water's next permanent assistant administrator.

Senate Republicans have suggested that they will place "holds" blocking all EPA nominees from proceeding to further hearings or confirmation votes until agency Administrator Gina McCarthy answers questions that GOP senators submitted to EPA long ago on a wide range of controversial rulemakings.

Burke is one of a few of the nominees who has had an EPW confirmation hearing, answering questions from senators in person in early June. After that hearing, senators had the chance to send the nominee further written queries. Burke's response includes replies to those questions, which were mostly submitted by EPW Chairman Sen. James Inhofe (R-OK) but also includes several questions from fellow EPW member Sen. Jeff Sessions (R-AL).

Burke, a former New Jersey Department Environmental Protection official and most recently a dean of public health at Johns Hopkins University in Baltimore, was first nominated to be EPA's assistant administrator (AA) for ORD in 2013. Burke joined the agency last January as the agency's Science Advisor and as a deputy AA to ORD, both roles that do not require Senate confirmation unlike the ORD chief position which does.

Dual Roles

Inhofe in his questions asked Burke about the dual role he is currently seeking as both science advisor and ORD chief. EPA has received advice from National Academy of Science (NAS), the Government Accountability Office and its Science Advisory Board (SAB) recommending that EPA split the dual role and have separate people undertake the two jobs -- both to reduce workload and to address real or perceived conflict that can arise between ORD and science staff in regional or program offices. EPA has long resisted the advice, and only briefly in recent years -- during former Administrator Lisa Jackson's tenure -- had separate individuals filled the two roles.

Burke responds that he and McCarthy consulted with NAS and believe that its recommendations would be fulfilled by the dual roles. "Having served as the Deputy Assistant Administrator and the EPA Science Advisor since January of this year, it is clear to me that it is possible for the AA of ORD to direct the world-class research program in ORD and serve as the EPA Science Advisor," Burke writes, adding, "[T]here is an important advantage to this model," citing ORD's alignment with EPA's mission and experienced scientists supporting the ORD chief.

"EPA has a built-in mechanism that would provide a check on any potential or perceived conflict of responsibility -- the Science and Technology Policy Council (STPC) -- a group of senior . . . EPA representatives that provide input on science and technology policy issues and ensures that EPA's science is well-coordinated," Burke adds.

Inhofe also questioned Burke whether EPA has followed advice from a 2004 NAS report cautioning the agency against reliance on old data when developing new national ambient air quality standards (NAAQS).

Burke responds that he agrees with NAS that "NAAQS decisions must be based on the best possible science and am pleased to find that this is the case. After the 2004 NAS report, EPA revised the process to evaluate the science . . . the 2011 [NAS] report . . . complimented the revisions to the NAAQS documentation and review process."

Some of Inhofe's questions touch upon legislation that Republicans are pushing to require publication of all studies that EPA and other agencies use in decision-making, or altering the make-up of EPA's SAB, a panel of independent, external science advisors to include more industry and state and local officials.

On the issue of making agency science "transparent," Burke responds by describing a database where EPA offices can store data and make it publicly available, as well as a policy on data access.

Inhofe also pressed Burke to "increase the participation of industry scientists and scientists from American heartland" on the SAB, arguing that "most SAB members are from academic institutions on both coasts." Burke, a former SAB member, responds that the board's existing membership includes 32 percent with industry or consulting experience, 13 percent with state, local government or tribal experience and that 11 of the 45 members of the chartered SAB reside in Midwestern states.

'Tremendous Resource'

Burke describes SAB as a "tremendous resource" and adds that he has started discussions with STPC "to ensure that the highest priority, cross-agency science questions are identified and that the agency takes full advantage of its SAB as a source of advice on those questions."

Inhofe also questioned Burke regarding changes underway with EPA's influential and often controversial IRIS program. IRIS analyzes environmental contaminants' human health risks, and provides cancer and non-cancer risk estimates that often form the basis for EPA waste, water and air decisions, and are consulted by other agencies world-wide as well. But the program has long been under scrutiny by regulated entities, Congress and the GAO for its lengthy, convoluted process and assessments that industry considers too strict.

Inhofe raised one concern that has been growing among regulated entities as the agency has in recent years undertaken assessments of chemicals like ethylene oxide, formaldehyde and methanol that are produced endogenously -- within the body -- as well as exogenously by industrial processes. Industry has urged the IRIS program to draft new guidance on the issue and to reality check these and other IRIS assessments.

"Do you agree that when ORD programs assess potential risks from such substances, it's critical to derive the range of potential risks arising from both sources -- internal and environmental -- and to communicate the degree to which these estimated risks from internal and external sources are plausible and realistic?" Inhofe asked.

"This is an important consideration in understanding and managing incremental risk from environmental exposure," Burke replies. "Since there are many natural products of metabolism that may have toxic effects if they are out of balance, the fact that they are produced naturally does not make them 'safe' at all doses."

Inhofe also raised another long-standing concern, saying that EPA's 2011 IRIS assessment of the solvent trichloroethylene, a frequent contaminant at Superfund sites and groundwater sources, is too strict, based on a short-term health effect of fetal cardiac malformations, and leads to overly stringent cleanup requirements, particularly when it intrudes onto sites as a vapor.

But Burke responds that an IRIS assessment "does not dictate how risk managers use scientific information in decision-making."

IRIS Agenda

Meanwhile, Burke commits to release "a prioritized IRIS agenda covering the next several years' effort" in response to another question about the program. IRIS leaders have been promising the release of such a five-year prioritized plan of IRIS assessments for some months, but that plan has yet to be released.

Inhofe also questioned Burke about NAS recommendations for use of transparent, systematic evaluation of studies included in IRIS assessments, and Burke indicates the program is evaluating different approaches to do so. He adds that if confirmed by the Senate, he will work with the program to "improve its methods for study evaluation and integration."

Echoing industry concerns about environmentalists urging the IRIS program to include study funding source as an element of its systematic reviews of toxicity literature, Inhofe asks Burke's views on the subject.

Burke replied that he will ensure clear criteria are used for judging study quality and integrating the information, and not authorship or funding source.

Elsewhere in his questions, Inhofe raised concerns over EPA's human testing program, which has been under scrutiny for some years, and is currently under NAS review.

Inhofe questioned whether EPA has complied with all the recommendations made in an EPA Inspector General (IG) report on the program last year, and whether testing on children is ever justified.

Burke responds that "all corrective actions have been implemented" in response to the IG's report, adding that "there are some things you can only learn by interacting directly with people, controlling variables and methods to allow firm conclusions to be drawn."

His response regarding exposing children to environmental pollutants does not mention an observational study of children's everyday exposures EPA sought to fund a decade ago, but canceled due to concerns from Sen. Barbara Boxer (D-CA), the ranking member of EPW. Burke does appear to try to alleviate the concerns raised with that aborted 2005 study grant.

"There's an important difference between observational studies of populations and intentionally dosing humans with a pollutant," Burke replies. "EPA does not intentionally expose children to pollutants. However, EPA has funded some important epidemiological studies that include children . . . This research ultimately helps the EPA to better understand how to protect children from the harmful effects of pollutants." -- *Maria Hegstad* (mhegstad@iwpnews.com)

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